

REMARKS

Claims 1-13, 79-82 and 93-108 are pending in this application. Claims 5-13, 79-82, 94-96, 101-103 and 105-108 have been allowed. Claims 1-4, 93, 97-100 and 104 have been rejected under 35 U.S.C. §103(a). None of the claims have been amended in this submission.

REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 1-4, 93, 97-100 and 104 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,057,165 to Mansour (hereinafter “Mansour”) in view of U.S. Patent No. 6,720,191 to Goldstein et al. (hereinafter “Goldstein”).

Applicants traverse this rejection.

1. Requirements for a prima facie case of obviousness.

“To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.” MPEP §2143.

2. There is no suggestion or motivation to combine or modify the prior art because the proposed modification/combination renders the prior art invention being modified unsatisfactory for its intended purpose.

Applicants maintain that the first criterion for establishing a prima facie case of obviousness is not met. The first criterion requires some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. “If the proposed modification would render the prior art invention being modified unsatisfactory

for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” MPEP §2143.01(V). *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). **Because the proposed combination/modification by the Office changes the Mansour device into a non-flow-through device, the invention is thereby rendered unsatisfactory for its intended purpose.** Therefore, there is no suggestion or motivation to make the proposed modification and a prima facie case of obviousness is not established.

3. The Office’s proposed modification/combination of prior art.

The Office states as follows:

Mansour differs from the instant invention in that the amended claims recite that the carrier closes the first opening so that fluid flow is prevented through the bottom surface of the carrier.

Office Action at pg. 3. The Office proposes the following modification:

Goldstein et al. teach an alternative carrier to the absorbent carrier disclosed in Mansour. It would have been obvious to one of ordinary skill in the art to incorporate the pressure-sensitive adhesive carrier into the carrier receiving device of Mansour **to provide a means of capturing and analyzing a different type of sample (such as a solid sample) that would not be possible with the absorbent carrier disclosed by Mansour.** Such modification would involve mere substitution of one known type of carrier for another known type of carrier as discussed in MPEP 2144.07.

Office Action at pg. 3 (emphasis added). The Office proposes to modify Mansour by substituting the adhesive carrier of Goldstein for the carrier in Mansour. The Office states that the modification would “provide a means of capturing and analyzing a different type of sample (such as a solid sample) that would not be possible with the absorbent carrier disclosed by Mansour.” Office Action at pg. 3. This statement is evidence of impermissible hindsight used by the Office because there is no disclosure, teaching or suggestion in Mansour to capture and analyze a different type of sample such as a solid sample. Because Mansour did not contemplate capturing and analyzing something outside the scope if its invention, there can be no teaching or suggestion found

in Mansour to the contrary. The teaching or suggestion to make the claimed combination must be found in the prior art not in applicant's disclosure. MPEP §2143. *In re Vaeck*, 947 f.2D 488, 20 USPQ2D 1438 (Fed. Cir. 1991). That which the Office states is not possible to accomplish in the prior art is part of the subject matter of novelty of the present invention. Mansour does not disclose, teach or suggest using a different type of sample such as a solid sample. For these reasons, the present invention is not obvious.

The Office's proposed modification changes Mansour into a non-flow-through device. This modification renders Mansour useless for its intended purpose as a flow-through device. In support of this assertion, applicants will show (1) that Mansour is a flow-through device, (2) that Goldstein's adhesive carrier does not provide for reagents to flow through, (3) that the proposed modification would change Mansour into a non-flow-through device, (4) that such modification would require substantial reconstruction and redesign of the structural elements shown in Mansour, (5) that such modification would also change the functional features of Mansour and the basic principle under which the Mansour construction was designed to operate, (6) that the proposed modification requires substantial reconstruction and redesign of the structural elements shown in Goldstein, and (7) that such modification would also change the functional features of Goldstein and the basic principle under which the Goldstein construction was designed to operate. For all of these reasons, the independent claims and their respective dependent claims are nonobvious and in a condition for allowance.

4. Mansour is a flow-through device.

The device in Mansour is a flow-through device. The title of the Mansour patent is "Quality control procedure for membrane flow-through diagnostic assay devices." The Mansour specification states that "[a] need has existed for a flow-through assay device...." Mansour, col. 3, lines 3-4 (emphasis added). A look at the Mansour claims reveals several limitations that require flow-through of liquids. And, the previous responses to office actions have pointed out citations where flow-through in Mansour is required. It is clear that the purpose of Mansour is to provide a flow-through device.

5. Goldstein adhesive tape is not a flow-through material.

In contrast to the flow-through device of Mansour, there is no disclosure, teaching or suggestion in Goldstein of a flow-through device. There is also no disclosure, teaching or suggestion in Goldstein for reagent to flow through the Goldstein carrier. In fact, Goldstein teaches away from the Office's proposed combination by disclosing a non-porous adhesive film (e.g. EVA polymer). Goldstein, col. 1, line 28. In one embodiment, Goldstein discloses a strip of tape substrate. “[C]oated tape 18A is shown constructed from, e.g., polyester films such as Mylar® having discrete and spaced apart coated spots 52 placed on coated side 19 of the tape.” Goldstein, col. 7, lines 53-56. The coated tape does not permit flow-through of reagents. In yet another embodiment of Goldstein, spokes 79 of an array 78 with an adhesive coating 76 are disclosed with respect to FIG. 8 and shown in FIG. 8. In another embodiment, a comb-like structure is disclosed with a coating on the end of each comb finger 84 as shown in FIG. 9. Goldstein, col. 8, lines 51-69. A breaker solenoid 94 breaks off a piece of the spoke and the broken off spoke portions 92 are deposited within a container as shown in FIG. 12. Goldstein, col. 9, lines 1-7. The broken off spoke portions are not flow-through pieces. It is clear that Goldstein does not disclose, teach or suggest a porous coating, tape, substrate or other carrier that would permit reagent to flow through.

6. The Office's proposed modification/combination would change Mansour into a non-flow-through device.

The Office's proposed modification is to take the Goldstein adhesive and substitute it for the carrier in Mansour. As shown above, Mansour is a flow-through device and Goldstein's tape is not. Hence, modifying Mansour to incorporate the tape of Goldstein into Mansour would no longer make Mansour a flow-through device and would render Mansour useless for its intended purpose as a flow-through device.

Because the proposed combination/modification by the Office changes the Mansour device into a non-flow-through device, the invention is thereby rendered unsatisfactory for its intended purpose. Therefore, there is no suggestion or motivation to make the proposed modification and a prima facie case of obviousness is not established.

7. There is no suggestion or motivation to combine or modify the prior art because the proposed modification/combination requires a substantial reconstruction and redesign of the elements of Mansour.

The flow-through concept of Mansour is an important feature of Mansour that cannot be negated. The flow-through structural features in Mansour include (1) an absorptive layer 44, (2) a porous spacer layer 43, (3) a flow control layer 42, (4) a porous membrane 41 and (5) teeth-like projections 49 to provide air spaces 50 for ventilation in the Mansour carrier. Making the modification/combination to Mansour as proposed by the Office would not only make Mansour no longer a flow-through device but also, in doing so would render at least all five of the above-listed structural features entirely useless and as a result, render the Mansour invention unsatisfactory for its intended purpose. Hence, making the proposed modification does not merely include a mere substitution as stated by the Office, but involves a complete restructuring of the Mansour carrier to remove the absorptive layer 44, remove the porous spacer layer 43, remove the flow control layer 42, remove the porous membrane 41 and redesign Mansour carrier to remove the projections 49 and air spaces 50. The suggested combination of references would require a substantial redesign of the elements shown in the primary reference as well as a change in the basic principle under which the primary reference was designed to operate. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP §2143.01(VI).

8. There is no suggestion or motivation to combine or modify the prior art because the proposed modification/combination changes the principle of operation of the prior art.

Not only are the structural features of Mansour negated by the Office's proposed modification requiring substantial redesign and reconstruction of the structural features of Mansour as illustrated in the above paragraph, but also, various functional features served

by the Mansour device are also negated. Negation of these functional features changes the principle of operation of Mansour. For example, Mansour states:

The absorbent layer also functions to provide a driving force (e.g., a concentration differential) which causes reagents applied to the test area of the assay device to flow into the absorbent layer.

Mansour, col. 5, lines 10-13. Providing a driving force for fluids is a functional feature of the absorbent layer. This functional feature is completely changed by the Office's proposed modification/combination. Hence, the function of a driving force provided by the absorbent layer is negated by the Office's proposed modification which changes the principle of operation of Mansour. As a result of the modification, the Mansour no longer operates such that a driving force is provided by the absorbent layer. As a result, there is no driving force at all. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. MPEP §2143.01(VI).

Yet another functional feature of the Mansour device that is negated by the Office's proposed modification is flow-through of unbound tracer. Mansour at col. 5, lines 18-24 states:

In addition, since the assay composite is employed in a manner such that the assay reagents flow through its layers, the porous membrane has a pore size which is greater than the size of the particulate label employed in the assay so that portions of the tracer, which do not become bound under assay conditions, flow into the absorbent layer and are not visible at the test area.

A part of the basic principle of operation of the Mansour device is to allow tracer that is not bound to the binder to flow through into the absorbent layer. An advantage of this basic principle of operation is that excess tracer is not visible at the surface test area. The Office's proposed modification/combination does not take into consideration this functional feature which is lost by proposed modification. Hence, not only the structural feature of the Mansour device as a flow-through device is negated by the Office's

proposed modification but also, the functional feature of the Mansour device is also negated. Therefore, a *prima facie* case is not established.

Another basic principle of operation of the Mansour device that is changed by the Office's proposed modification is the control of the rate of flow of reagents. Mansour states:

Thus, in effect, the flow control layer functions to reduce the rate of flow of assay reagents through the more porous test area. The pore size of the flow control layer, as well as the thickness of the flow control layer, is preferably controlled in a manner such that the flow of assay reagents through the test area provides the requisite sensitivity as well as a rapid and accurate assay.

Mansour, col. 5, lines 35-41. There is no other disclosure, suggestion, or motivation for how to otherwise meet the basic operation of Mansour to control the flow rate of fluids in order to provide the requisite sensitivity as well as a rapid and accurate assay. Because Mansour's intended purpose of controlling the flow rate is negated, there can be no suggestion or motivation for the Office's proposed modification and a *prima facie* case is not established.

Additional steps in Mansour's invention are rendered useless by the Office's proposed modification. These steps include:

- (1) The flow through of tracer discussed above.
- (2) The flow through of wash solution ("Similarly, after addition of the tracer, a wash solution may be applied to the test area 60 to wash any tracer which may not be specifically bound to the complex in the test area 60, into the absorbent layer 44." Mansour, col. 12, lines 14-17.).
- (3) The flow through of sample ("...the analyte positive control sample contacts all of the binder in the test area 48, with the sample flowing through to the absorbent layer 44." Mansour, col. 12, lines 28-29.).

These above-listed steps no longer serve any function as a result of the Office's proposed modification. As a result, the basic principle of operation of Mansour changes such that there is no flow through of reagents. Yet, there is nothing in the prior art to disclose, teach or suggest the changes to be made. Therefore, there is no suggestion or

motivation to make the proposed modification/combination and, as such, no basis for establishing a *prima facie* case of obviousness.

9. There is no suggestion or motivation to combine or modify the prior art because the proposed modification/combination requires a substantial reconstruction and redesign of the elements of Goldstein.

Applicants would also like to point out that the Office's proposed modification/combination would require a substantial reconstruction and redesign of the elements of Goldstein. Firstly, there is no disclosure, teaching or suggestion in Goldstein to fashion the Goldstein carrier into something that would fit the Mansour device. Secondly, if the Goldstein carrier was fashioned into something that would fit the Mansour device, it would require reconstruction and redesign of the Goldstein carrier. For example, in one embodiment of the Goldstein carrier, the carrier is a tape which is flexible and flimsy. It would have to be adapted such that it would snap to the Mansour cover.

In another embodiment, the Goldstein carrier is a spoke which is broken off (see FIGs. 8 and 12). To adapt this embodiment of the Goldstein carrier to fit the Mansour cover would require substantial reconstruction and redesign not only of the broken off piece but also, of the basic principle of operation of the daisy wheel which is used for obtaining sequential transfers in Goldstein. The principle of operation of Goldstein which involves breaking off pieces to carry them to analysis would be changed because it is highly unlikely that a broken off piece would suitably fit the Mansour cover. Hence, even use of a daisy wheel and the step of breaking off a piece, both principles of operation, would have to be changed.

In yet another embodiment, the Goldstein carrier is a comb with comb fingers. To adapt this embodiment of the Goldstein carrier to fit the Mansour cover would require substantial reconstruction and redesign not only of the carrier but also of the basic principle of operation of obtaining samples using the comb instrument. All of these illustrations show that Goldstein, in fact, teaches away from the making the modification proposed by the Office.

10. The prior art does not teach or suggest all of the claim limitations.

In order to establish a prima facie case of obviousness, the prior art must teach or suggest all of the claim limitations. The prior art does not disclose, teach or suggest all of the claim limitations. In particular, the prior art does not disclose, teach or suggest the claim limitation of a carrier that mates with the carrier-receiving portion, closes the first opening, seals the first opening to prevent fluid flow through the bottom surface, and forms a reservoir. As is evident in FIG. 12 of Goldstein, the Goldstein reference does not disclose, teach or suggest this claim limitation. In fact, Goldstein teaches away from this limitation by disclosing dropping the broken off pieces into a vessel without using the carrier to seal or close the opening of the vessel.

Similarly, Mansour does not disclose, teach or suggest at least the claim limitation of fluid prevented to flow *through* the bottom surface or *through* the first opening. The independent claims require the carrier to close the first opening. This limitation is not found in Mansour. In fact, Mansour teaches away from this limitation by disclosing a flow-through device. Fluid flows out of the reservoir in Mansour through a system of porous and flow control layers that close the reservoir opening. “The assay composite 40 is comprised of a *porous membrane* 41...” Mansour, col. 11, lines 7-8. The porosity of the composite is discussed in Mansour at col. 11, lines 5-17. “Adjacent to the lower surface of the porous membrane 41 is a *flow control layer* 42 which is preferably formed from a *unidirectional flow-controlling* polycarbonate membrane having a pore size of 0.6 micron.” Mansour, col. 11, lines 14-17. “*Immediately underneath the flow control layer is a porous spacer layer 42 which generally has a pore size greater than the pore size of flow controlling layer 42.*” Mansour, col. 11, lines 18-20. “Immediately underneath the porous spacer layer 43 is *absorptive layer* 44.” Mansour, col. 11, lines 22-23.

Clearly, in Mansour the reservoir is not sealed and fluid is allowed to flow through the various porous and flow-control layers. Actually, there is nothing even beyond the absorptive layers to further contain fluid flow within the reservoir at that end. In fact, spaces are provided to ventilate the assay composite 40. See Mansour at col. 11, lines 46-50 (“The cover 46 is supported over porous membrane 41 by teeth-like projections 49 extending upward from the sides of the base 45. The projections 49 are of sufficient height to provide *air spaces 50 which provide for ventilation of the sides of the*

*assay composite 40.”). Mansour’s device peculiarly ventilates the assay composite which according to the Office is an equivalent to the sample. ***In such a construction, fluid flows into, through and past the sample and even capably beyond them and through the spaces 50 in Mansour.*** Therefore, Mansour is quite different from applicants’ invention as claimed and does not disclose, teach or suggest the aforementioned claim limitation of preventing fluid flow through the bottom surface.*

11. Dependent claims 4, 97 and 104

Dependent claims 4, 97 and 104 were also rejected by the Office. These claims recite that specifically transferred material transferred by microdissection is present on the carrier and that at least a portion of such specifically transferred material is included in the reservoir. Mansour and Goldstein do not disclose, teach or suggest the limitation of specifically transferred material transferred by microdissection and non-specifically transferred material being located on the carrier wherein at least a portion of the non-specifically transferred material is excluded from the reservoir and a portion of the specifically transferred material is included in the reservoir. Because a claim is obvious only if each and every element as set forth in the claim is disclosed, taught or suggested in the prior art and because Mansour and Goldstein do not disclose, teach or suggest the aforementioned claim limitations dependent claims 4, 97 and 104 are not obvious in light of the prior art and are in a condition for allowance.

12. Dependent claims 3 and 98

The Office rejected dependent claims 3 and 98 as being obvious in light of Mansour and Goldstein. Applicants traverse this rejection. The Office on page 3 of the Office Action states that

Mansour further discloses that a well (10) may be mated with the cover at the conduit for delivering fluids into the conduit (col. 12, lines 1-7).

Applicants would like to point out that even though Mansour calls item (10) a well, the well includes an opening in the top and an opening in the bottom. At col. 10, lines 49-50, Mansour states:

An opening 14 in the bottom 13 allows a fluid in the well to flow out.

Therefore, the well (10) of Mansour is not able to contain fluid and is different from the vessel recited in the claims. The dictionary definition of the word vessel obtained from the Internet website www.dictionary.com is:

1. A hollow utensil, such as a cup, vase, or pitcher, used as a container, especially for liquids.

It is not understood how the well alone of Mansour is used as a container or vessel when it has an opening 14 in the top and in the bottom that allows fluid in the well to flow out. Hence, dependent claims 3 and 98 are believed to be non-obvious.

13. Dependent claim 99

The Office rejected dependent claim 99 as being obvious in light of Mansour and Goldstein. Mansour does not recite or anywhere in the specification disclose, teach or suggest a centrifuge tube or microtiter plate. There is no mention of a centrifuge tube or microtiter plate in the above-referenced quotation from or anywhere in the specification of Mansour. In fact, Mansour teaches away from using a centrifuge tube or microtiter plate by disclosing a well (10) that has two openings—one in the top and one in the bottom that allows fluid to flow out. Goldstein depicts a test tube 66 in FIG. 12; however, there is no disclosure, teaching or suggestion that this test tube mate with the second end of the extraction device as required in this claim via dependent claim 98. Because Mansour and Goldstein do not disclose, teach or suggest a “centrifuge tube” or a “microtiter plate” as recited in claim 99, claim 99 is nonobvious and in a condition for allowance.

In view of the foregoing remarks, applicants respectfully submit that the application is in a condition for allowance, and action toward that end is earnestly solicited. The Office is invited to contact the applicant's representative at the number below to facilitate prosecution of this application.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time.

Respectfully submitted,

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